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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,227	11/12/2003	John D. Pruitt	029318-0985	3550

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/28/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/705,227	PRUITT ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17, 19-37 and new claims 38-57* is/are pending in the application.

4a) Of the above claim(s) *27 and 31-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-26,28-30 and 37-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 2/29/08. Claims 1, 19, 25, 37 are amended. Claim 18 is canceled. New claims 38 to 57 are added. Claims 1-17 and 19-57 are pending. Claims 27 and 31-36 are withdrawn from consideration.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn.

Claim 18 is canceled and the limitations moved into claim 1. Applicant has indicated that the particle size in 18 is not taught by any of the cited prior art references and as such the rejections of the claims under 102(b) over Murakami et al. (US 6,287,596) or Shimizu et al. (US 6,299,904) or Martyn et al. (in WO 00/50013) should be withdrawn. However, it is brought to applicant's attention that claim 18 was rejected under 35 USC 103 and as such the rejections over Murakami et al. (US 6,287,596) are modified below to include all the claims that are rendered obvious by Murakami in view of the amendments.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-17, 19-26 and 28-30 and 37 and new claims 38-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murakami et al. (US 6,287,596).

Murakami discloses fast disintegrating compression molded product/tablet (abstract; column 4, lines 24-63; column 7, lines 11-15) comprising pharmaceutically active agents listed in column 5, line 61 to column 6, line 67 meeting the requirements of claims 1, 26, 30 and 56; for example, ibuprofen (column 6, line 3) is slightly or poorly water soluble meeting claim 52 and diphenhydramine hydrochloride (column 6, line 5) is soluble in water meeting claim 51, lubricants, diluents, coloring agents with the diluents being lactose or glucose or sucrose and the binders being acacia or pullulan or polyvinylpyrrolidone, flavoring agents, effervescent agents such as combinations of tartaric acid, malic acid and sodium carbonate or sodium bicarbonate (column 7, lines 13-45), and the pullulan and the effervescent couple meeting claims 1, 4, 5, 7-11, 14-16, 25 and 26 and 46. Claim 17 is the property of the product so that Murakami meets the claim. Friability is a property of the product; the disintegration time of the product of Murakami is in the order of seconds (column 9, lines 13-43) meeting claims 14 and 50; Murakami teaches that the rapidly disintegrating compression molded material is orally administered to infants and aged adults for the treatment of variety of diseases (column 9, lines 44-60; column 10, lines 34-40) meeting claim 37. Thus Murakami discloses a composition

containing pullulan, effervescent couple, lactose and active agent. The composition of Murakami also contains surfactants (column 7, lines 43-49) meeting claims 21 and 28-30. Regarding claims 1, 19, 20 and 37 active agents are generally obtained in powder forms (column 5, lines 54 and 57) and the particles of the powder have sizes that meet the limitations of claims 18-20, with powder meeting the amorphous particle limitation of claim 55. The sugar alcohols in Murakami are namely D-mannitol, D-sorbitol, xylitol, maltitol, anhydrous maltose, hydrous maltose, anhydrous lactitol, hydrous lactitol, and reducing malt sugar syrup. Of these, D-mannitol, xylitol, and multitol (column 4, lines 54-58) and other excipients such as starches and celluloses (column 4, lines 29-53) meet claims 4-8, 11, 40, 41, 43, 44 and 47. Claim 48 is a product by process claim such that Murakami meets the claim. Regarding the amounts of the active agent and surface stabilizer, the claims 22-24 would have been obvious because the ordinary skilled artisan have the capabilities to use desired amounts of active agents and surface stabilizers in the composition Murakami for a rapidly disintegrating material. No specific particle size is recited in Murakami except that the active agents are in powder forms prior to inclusion in the dosage form such that the powder would have small particles sizes. Therefore, taking the general teaching of the reference, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that using surface stabilizers and drugs in powder form and in appropriate and desired amounts would lead to solid dosage form that would have the anticipated rapid disintegration.

Response to Arguments

4. Applicant's arguments filed 2/29/08 have been fully considered but they are not persuasive.

5. Applicant argues that Murakami does not provide the particle size of the active agents and that the examiner cited no reference to provide reasoning why the powder active agents of the prior art would have particles within the recited range; that the examiner's reasoning is based on "obvious to try" and has not met the burden of establishing a prima facie case of obviousness.

The examiner agrees with applicant that Murakami does not specifically teach the size of the particles and that is why claims 1, 19 and 37 are not rejected under 35 USC 102 now in view of the amendment. It is also noted that applicant acknowledges in the remarks that Murakami states that: "No particular limitation is imposed on the pharmaceutically active ingredients which may be used in the present invention, and they may be added in accordance with intended uses in the form of powder" and thereby acknowledges that Murakami contemplates the use of powdered active agents in the formulation of the dosage forms. The examiners reasoning is not based on obvious to try because, "a large number of particles, either agglomerated or aggregated or both, is said to constitute a powder. Generally a powder is regarded as being constituted of particles in the size range of 0.1 to 1000 microns," as evidenced by Kawam et al. (US 5,098,698) at column 2, lines 56-60. This range in particle size for powders in general encloses the particles sizes recited in amended claims 1, 19 and 37. However, for the sake of argument, it may be noted that because powders have particles ranging in sizes of from 0.1 micron to 1000 microns, it would be reasonable to expect that powder drugs having any particle size within the expected particle size range would be suitable for use in the composition of Murakami with reasonable expectation of success that the dosage form would rapidly disintegrate as anticipated by Murakami. Further, applicant has not provided factual evidence that any active agent having particle size that is, greater than 0.2 microns, about 2 micron and/or less than 2 micron provides

unexpected results to the dosage form from which the particular active agent is made. In the absence of factual evidence, solid dosage forms prepared from drug particles having sizes of greater than 0.2 microns, about 2 micron and/or less than 2 micron are not patentable over solid dosage forms prepared from powder-drugs that would have any particle size of from 0.1 micron to 1000 micron, which is the particle size range of powder. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claims 13 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 19 are directed to solid dosage form and the requirement that the solid dosage form is an aerosol formulation in claims 13 and 49 is unclear since fluids are not solids. Clarification is respectfully requested.

Response to Arguments

8. Applicant's arguments filed 2/29/08 have been fully considered but they are not persuasive.

9. Applicant provided Appendix A, an article from an online Wikipedia entry for the term aerosol. Specifically the article says that aerosol comprises matter floating in air suspension in which solid or liquid or combined solid-liquid particles are suspended in a fluid. Specifically solid dosage forms are not aerosols, the aerosols may have suspended solid particles but the aerosol dosage form itself is not a solid dosage form such as tablet of capsule or pellet or bead or powder. Suspension is not a solid dosage form. For example, US 4,917,894 states that there are solid dosage forms such as lozenges and compressed tablets and non-solid dosage forms such as gargles, mouth washes, sprays and gels (column 1, lines 17-21), and further in column 3, lines 9-13 describes dosage forms including lozenge, compressed tablet or the like, or in dosage form other than solid, such as a gargle, mouthwash, oral rinse, spray, gel, aerosol. The American Heritage Dictionary, 2nd College edn ., 1982 at page 83 and 18th edn., of Remington's Pharmaceutical Sciences, 1990 at page 177 define aerosol as gaseous dosage forms.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Blessing M. Fubara/
Examiner, Art Unit 1618